D. D. N. J., F. D. C. 601–655 Issued February, 1943

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

601–655

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

Washington, D. C., November 11, 1942.

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DRUGS SEIZED BECAUSE OF POTENTIAL DANGER TO HEALTH WHEN USED ACCORDING TO DIRECTIONS

601. Adulteration and misbranding of Bromo-Caps; misbranding of Rx S368957 Filled Capsules. U. S. v. 5 Drums of Rx 368957 Filled Capsules and 111 Display Cards and 214 Cartons of Bromo-Caps. Default decree of condemnation and destruction. (F. D. C. Nos. 4900 to 4902, incl. Sample Nos. 50246–E, 50247–E.)

This case was based on the interstate shipment of a quantity of acetanilid, aspirin, and caffeine capsules in drums, a portion of which had been repackaged and labeled "Original and Genuine Bromo-Caps." The repackaged capsules would have been dangerous to health when used according to the directions on the carton. The labeling of the repackaged capsules also overstated the acetanilid content by approximately 50 percent and it bore false and misleading claims. The labeling of both bulk and repackaged capsules failed to bear adequate directions for use and warning and satisfactory ingredient statements.

On June 13. 1941, the United States attorney for the District of Maryland filed a libel against 5 drums containing a total of 31,800 Rx S368957 Filled Capsules; and 111 display cards each containing 24 4-capsule-sized cartons and 2 12-capsule-sized cartons, and 202 4-capsule-sized cartons and 12 12-capsule-sized cartons of Bromo-Caps at Baltimore, Md., alleging that the articles had been shipped on or about April 11, 1941, by Parke, Davis & Co. from Detroit, Mich., and charging that a portion were adulterated and misbranded and that the remainder were misbranded.

Analyses of samples of the article showed that it consisted essentially of acetanilid (2.3 grains), aspirin (4.4 grains), and caffeine (¾ grain) per capsule.

The repackaged capsules were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess, namely, (cartons) "Each Cap contains 3½ grs. acetanilid," since each capsule contained materially less than 3½ grains of acetanilid.

They were alleged to be misbranded: (1) In that they would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely: (Carton) "One Capsule Usually Gives The Desired Results. If Necessary, Another May Be Taken In One Hour"; and (circular) "Take one Bromo-Cap with a swallow of water and repeat again in about an hour if not relieved, or until 3 doses have been taken. * * * A few Bromo-Caps, taken one every 2 Or 3 hours * * * 1 Bromo-Cap every 3 or 4 hours. * * * take 1 Bromo-Cap. Repeat in 1 or 2 hours. Then one every 3 or 4 hours. * * * Take one Bromo-Cap every 3 or 4 hours with large drinks of water. * * * Take one Bromo-Cap, another in 1 hour, then one every 3 or 4 hours. It may be advisable to take at least 12 altogether * * * a Bromo-Cap every 2 or 3 hours for a few doses. * * * Bromo-Cap taken with one or two large glasses of water. Thereafter take one Bromo-Cap every three or four hours until well." (2) In that the name "Bromo-Cap" on the carton was false and misleading since they contained no bromine or compound of bromine. (3) In that the statements, (carton) "Bromo-Caps Contain No Narcotic Drugs" and (accompanying circular) "A Quick, Sure Scientific Remedy That Takes the Place of Aspirin, Habit-Forming Headache Powders and Liquids," were false and misleading since they created the impression that the article contained neither dangerous drugs nor aspirin. (4) In that statements in the labeling representing that they would give relief and constitute an adequate treatment for rheumatic pains, colds, toothache, overindulgence in food or drink, mental fatigue, menstrual pains, feverish conditions, and sea or car sickness, were false and misleading since they would not be efficacious for such purposes. (5) In that the labeling failed to bear the common or usual names of the active ingredients other than acetanilid and did not state the quantity or proportion of acetanilid present, since the statement on the label was incorrect.

Both the repackaged and bulk capsules were alleged to be misbranded: (1) In that their labeling failed to bear adequate directions for use (in the case of the repackaged capsules) since the directions given provided for the administration of excessive quantities of acetanilid; and (in the case of the bulk capsules) since the labeling failed to bear warnings to the effect that because of their acetanilid content, frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug, and that they should not be given to children. (2) In that the labeling did not bear adequate warnings against use in those pathological conditions or by children where their use might be dangerous to health or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users, since it failed to bear warnings to the effect that because of their acetanilid content frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug, and that they should not be given to children.

The bulk capsules were alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients, since aspirin had been declared by its chemical name, "Acetylsalicylic Acid," rather than by its common or usual name.

On August 18, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

602. Misbranding of cold capsules and tablets. U. S. v. 4,300 Cold Special No. 2 Capsules and 74 Packages of Swiss Capsules (and 2 other seizures of cold remedies). Default decrees of condemnation and destruction. (F. D. C. Nos. 3866, 4695, 4909, 4913. Sample Nos. 50188–E, 50189–E, 50249–E, 50250–E, 50668–E, 60421–E.)

These preparations, when used according to directions, would supply acetanilid in amounts that would be dangerous to health. Their labeling also failed to bear adequate directions and warning statements, and they were misbranded further because the name of a portion, "Cold Special," and the statement on the label of the remainder, "For Simple Colds * * * For * * * Colds," were false and misleading since they did not constitute a treatment or preventive for colds. A portion also failed to bear the required ingredient and quantity of contents statements, was deceptively packaged, and failed to bear the name and place of business of the manufacturer, packer, or distributor.